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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,994	BELHE ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,21,22 and 24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-6 and 24-29* is/are allowed.

6)☒ Claim(s) *7-18,21,22,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 7, 11-18, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Modesitt et al. (6,136,010). Modesitt et al. disclose, at least in figures 4-5, 11A-11E, and 13 and in col. 10, line 18 to col. 11, line 29; a vascular closure device and a method with the device for closing a vascular opening; where the device includes a needle (38 or 38'), a suture (34), a snare (40, see fig. 4, configured to grasp suture), the snare comprising a loop portion (tubular collar 50, see col. 7, lines 40-43); and a pre-tied knot (80), and an anchor (24) configured to extend through an opening in a blood vessel, the anchor being configured to move between the a contracted configuration where the anchor is sized to fit through the opening in the blood vessel and an expanded configuration where the anchor is too large to fit through the opening the blood vessel; where the loop portion of the snare is configured to receive a suture and needle combination (34 and 38) after the snare and the suture and needle combination are inserted through the wall of the blood vessel and to grasp the suture in the blood vessel and retract the suture through the vessel wall (see fig. 11c, where the needle (38) with suture (34) are inserted into the vessel), where the device includes firs and second needles (38, 38')—the first needle configured to insert suture through the

wall of the blood vessel and the second needle configured to insert the snare through the wall of the blood vessel (i.e., the snare is moved from inside the blood vessel and through the wall--see fig. 11D), where a suture (34) is configured to move with the needle from a retracted position to an extended position, where a portion of the suture extends lengthwise from a tip of the needle toward a proximal end of the device and outside of the needle (see fig. 11A), where the method includes inserting a sheath (12) into a vessel, inserting a snare (40 and/or 42) and a needle (38) on a first side of a vessel opening, inserting a suture (34) and another needle (38') on a second side of the opening, positioning the needle with suture inside the loop portion of the snare after inserting the snare and the needle with suture into the vessel (see fig. 11c, where the needle (38) with suture (34) are inserted into the vessel), grasping the suture with the snare, pulling the suture across the vessel opening (see fig. 11d), directing the distal end of the suture and a needle (38) through a pre-tied knot (80) at a proximal end of the suture, cinching the knot or tightening the suture, disengaging and withdrawing the sheath (12) from the vessel opening; where the device is secured in the blood vessel (via 24), where the sheath is anchored in the vessel with a pair of extendable feet (24a and 24b or 22 and 24), and where a safety wire (GW) can be inserted into the vessel opening and be used to facilitate reinsertion of the sheath.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (5,728,114). Evans et al. disclose the invention substantially as claimed. Evans et al. disclose, at least in figures 7-12 and in col. 7, line 28 to col. 8, line 20; a vascular closure device including an anchor (22) configured to extend through an opening in a blood vessel, the anchor being configured to move between a contracted configuration (see fig. 10), where the anchor is sized to fit through the opening in the blood vessel and expanded configuration (see fig. 11) where the anchor is too large to fit through the opening in the blood vessel, a snare (42) configured to be inserted through a wall of the blood vessel at a location that is adjacent to the opening in the blood vessel (within the blood vessel) and comprising a loop portion; a suture (24) configured to be inserted through the wall at another location adjacent the opening, the snare also being configured to grasp the suture in the blood vessel and retract the suture through the wall of the blood vessel, where the device is configured to close the opening in the blood vessel (see figs. 9-11), where the snare comprises a wire loop (42)

having a memory that causes the loop to open in a repeatable orientation (i.e., the loop is flexible), where the snare and the suture each move between a retracted position and an extended position to allow the snare and the suture to be inserted through the wall of the blood vessel (from within the blood vessel), and where the device further comprises a handle set (26 and 28) to allow an operator to control movement of the snare and the suture.

However, Evans et al. do not specifically disclose (in figures 7-12) that the vascular closure device includes a suture and needle combination. Nevertheless, Evans et al. teach, at least in figures 26-31 and col. 13, lines 30-64; a suture (208) and needle (206) combination. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a needle with suture 24. Such a modification would allow the suture to be manipulated for closing the opening in the blood vessel, where a needle would be used for tissue penetration and grasping (e.g., with forceps).

5. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (5,722,981) in view of Kammerer (5,562,684), and further in view of Burbank et al. (6,648,286) . Stevens discloses the invention substantially as claimed. Stevens discloses, at least in figures 7(a)-7(c); a vascular closure device, where the device includes first and second needles (112, 113) configured to move between retracted and extended positions, a suture (121) configured to move with the first needle, and a snare (119) configured to move with the second needle, the snare including a wire loop having a memory; where the wire loop opens adjacent to the first needle to grasp the suture

and is configured so that the suture is positionable inside the wire loop of the snare. However, Stevens does not disclose a pre-tied knot disposed on a proximal end of the suture such that a distal end of the suture can be directed through the pre-tied knot. Kammerer teaches, at least in figures 16-25, a suture (100) with a pre-tied knot (102) on its proximal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer, to include a pre-tied knot with the suture of Stevens's device. Such a knot would allow a quick and convenient means for tying and tightening a suture around tissues to be joined together.

However, Stevens in view of Kammerer does not disclose that the first needle is positionable in the wire loop after the first and second needles move to an extended position, and where the wire loop grasps the suture after the first needle is removed from the inside the wire loop. Burbank et al. teach, at least in fig. 7-13 and col. 7, lines 38-52; a needle-like element (136) that is positionable in a wire loop (124) configured to accommodate the needle-like element. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Burbank et al., to configure the wire loop of Stevens in view of Kammerer, so that the first needle is positionable in the wire loop of the snare. Such a modification would allow that the wire loop to be disposed at or on the distal end of the first needle and assuredly capture the suture moved through and out of the first needle or when the first needle is removed from inside the wire loop.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sierra et al. (5,496,332) in view of Kammerer (5,562,684). Sierra et al. disclose the invention

substantially as claimed. Sierra et al. disclose, at least in figures 2-6, a method of closing a vascular opening utilizing a vascular closure device, where the method includes inserting a sheath (12) into a vessel through a vessel opening, inserting a snare (34) into the vessel at a first location laterally adjacent to the vessel opening (i.e., the perimeter of the opening), the snare including a wire loop; inserting a suture (66 or 68) with a needle (46 or 48) into the vessel at a second location laterally adjacent to the vessel opening (see figs. 4-6) and into the wire loop, extending the wire loop across the vessel opening to grasp the suture; and pulling the suture across the vessel opening the through the vessel on the first side of the vessel opening. However, Sierra et al. do not disclose directing the distal end of the suture through a pre-tied knot formed on a proximal end of the suture to create a knot to approximate tissue. Kammerer teaches, at least in figures 16-25, a suture (100) with a pre-tied knot (102) on its proximal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer, to include a pre-tied knot with the suture of Sierra et al. and to direct the distal end of the suture through the pre-tied knot. Such a knot and method step would allow a quick and convenient means for tying and tightening a suture around tissues to be joined together.

Allowable Subject Matter

7. Claims 1-6 and 24-30 are allowed.

8. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a vascular closure device including, inter alia, first and second needles, a suture, a snare configured to move with

the second needle, and a pre-tied knot disposed on the proximal end of the suture, where the snare includes a loop portion configured to grasp the suture after the needles are in an extended position and the first needle and suture extend within the loop portion. Also, none of the prior art of record, alone or in combination, discloses a method of closing an opening in a blood vessel with vascular closure device, the method including, inter alia, inserting a needle and suture through a wall of a blood vessel, inserting a snare with a loop portion through the wall of the blood vessel at another location, and positioning the needle and snare within the loop portion, where the suture is grasped with the loop portion after removal of the needle from within the loop portion.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Amendment

9. Applicant's arguments filed on July 17, 2009 and regarding the rejection of claims 7-18, 21, 22, 30, and 31 have been fully considered but they are not persuasive. That is, with respect to claims 7, 11-18, 21, and 22, Modesitt et al. indeed disclose a loop portion of the snare being configured to receive the suture and needle combination after

the snare and the suture and needle combination are within the blood vessel (i.e., inserted through the wall of the blood vessel). Modesitt et al. also disclose that the device is configured for passing the loop portion through the wall of the blood vessel at a first location on the wall spaced laterally of a tissue puncture (from within the blood vessel) passing the suture and needle through the wall and into the loop portion.

With respect to the rejection based on Evans et al.: It would have been obvious to one having ordinary skill in the art to apply a needle with the suture after the snare and the suture and needle combination have been inserted through the wall of blood vessel. A needle would aid in the closure of the blood vessel, while the loop portion would be applied for grasping the suture and needle combination for a surgeon's manipulation.

With respect to the rejection of claim 30, base reference Stevens indeed discloses first and second needles moved to an extended position (within a patient's body), where it would be obvious, in view of Burbank et al., to move a needle from inside the wire loop, so that the wire loop may grasp the suture.

With respect to the rejection of claim 31, Sierra et al. indeed disclose inserting the snare through a vessel opening, where at least a periphery of the snare is moved and located at first location laterally adjacent to the opening, while a suture with a needle is inserted at second location laterally adjacent to vessel opening (which is shown to have a collapsed diameter). Moreover, the suture with the needle is inserted into the wire loop of the snare.

The objection to claim 1 is hereby withdrawn.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773